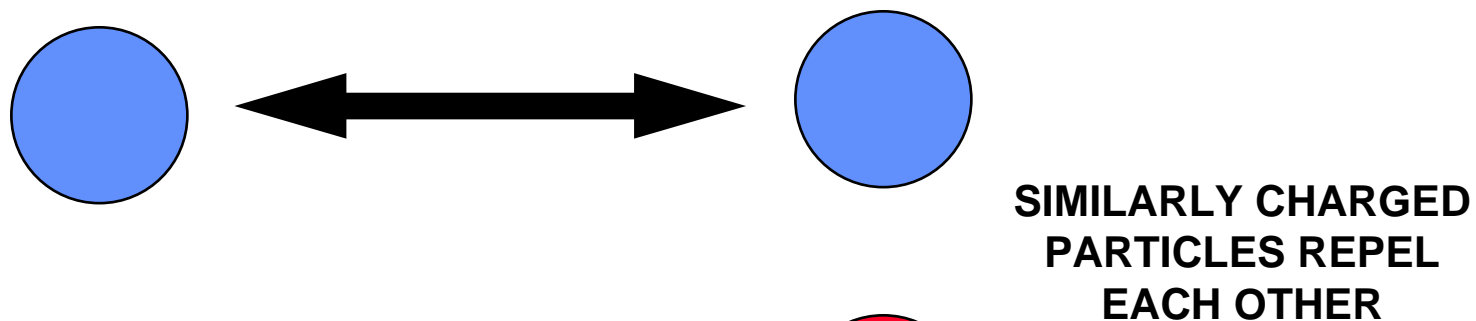
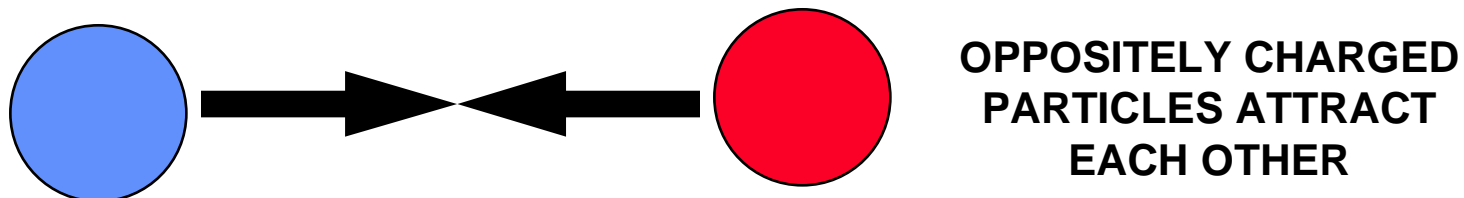


EXHIBIT A

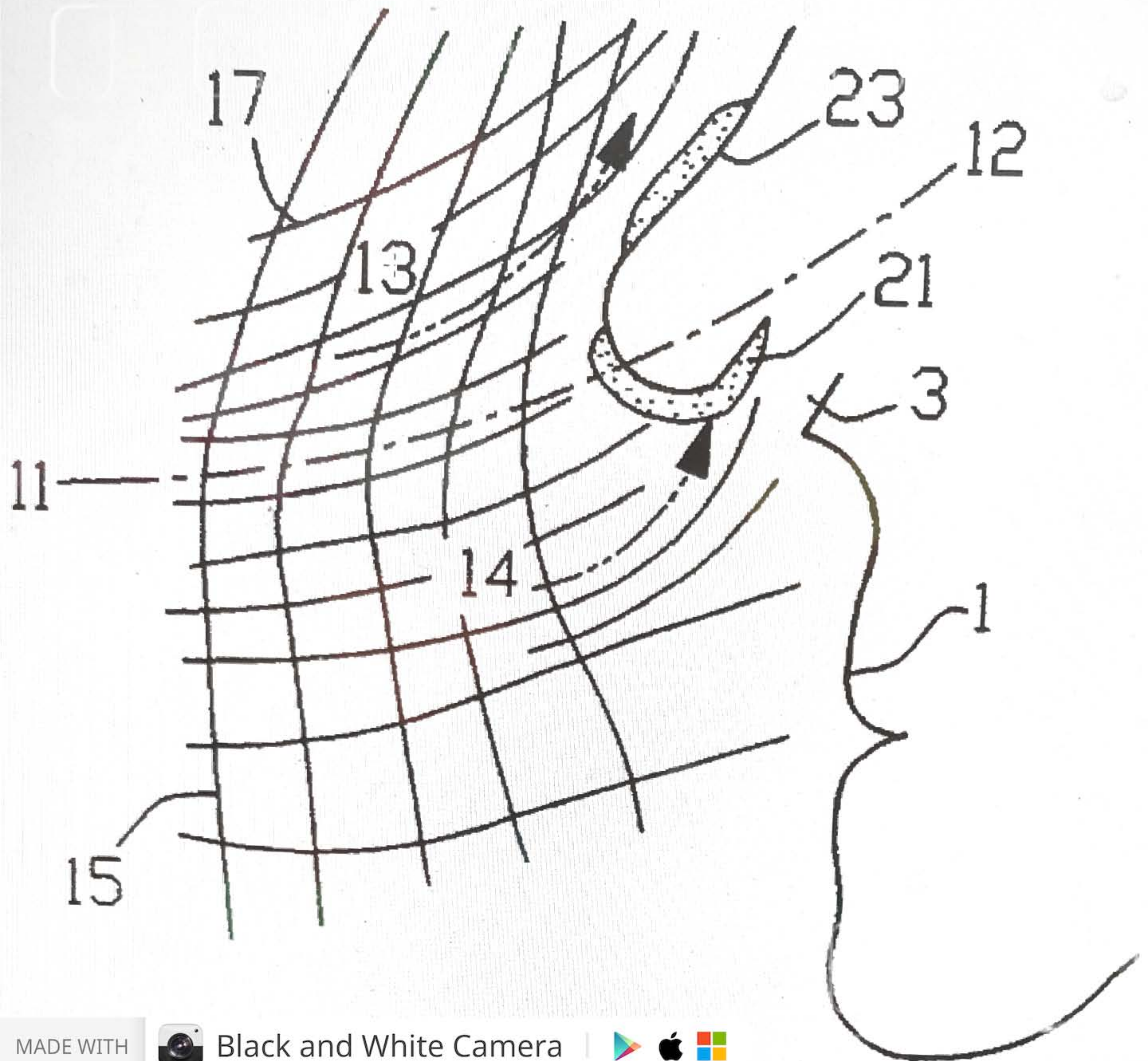
ASSERTED CLAIMS

- **Claim 1 – Independent Method Claim**
- **Claim 2 – Independent Formulation Claim**
- **Claim 6 – Formulation Claim Depends From Claim 2**
- **Claim 7 – Formulation Claim Depends From Claim 2**

ELECTROSTATIC ATTRACTION & REPULSION



2TMY



Positive Electrostatic Field

Attracts and Holds
Negatively Charged
Particles:

- Viruses & Bacteria
- Pollutants
- Dust
- Pollen



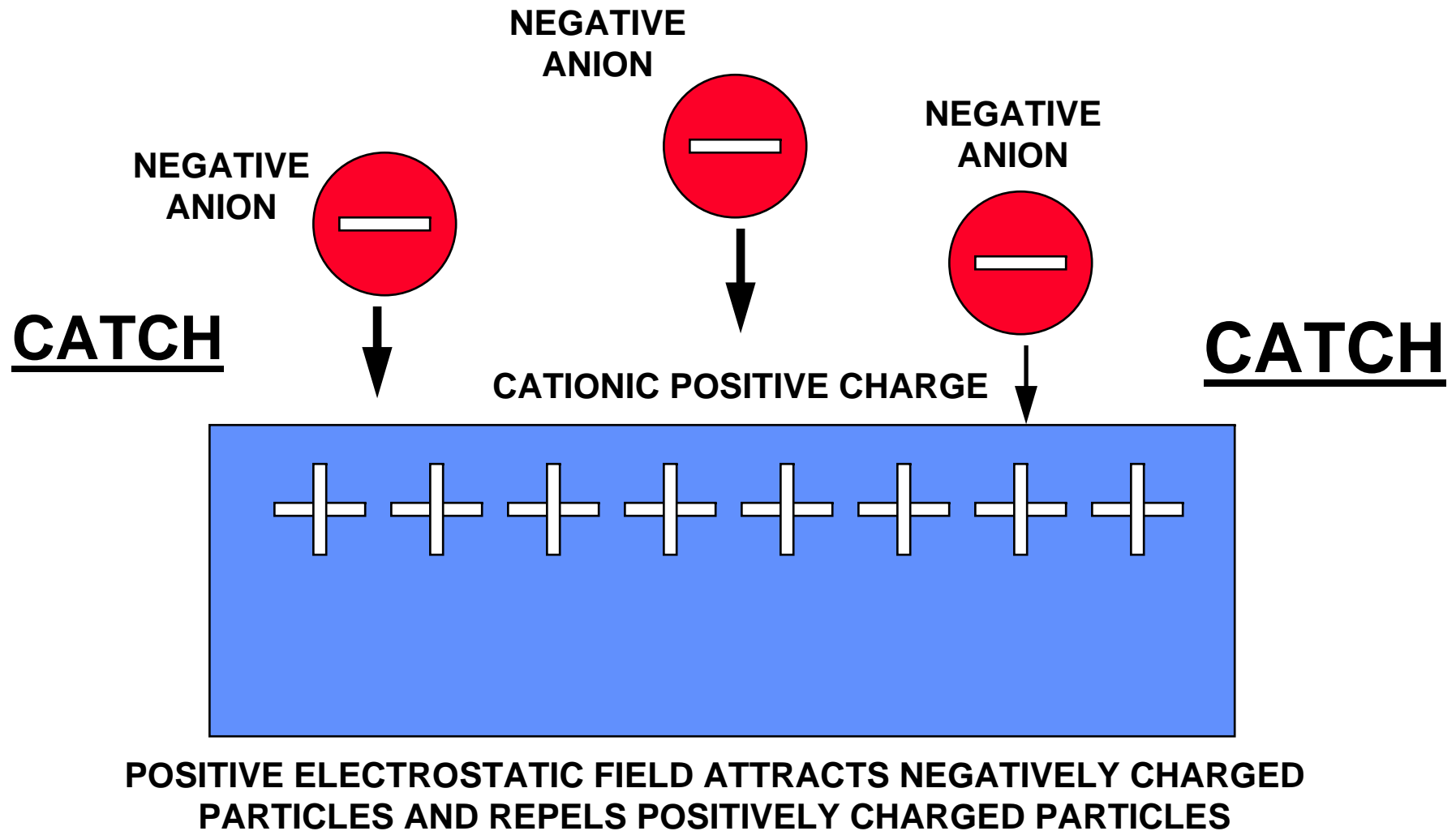
Claims Have 3 Elements:

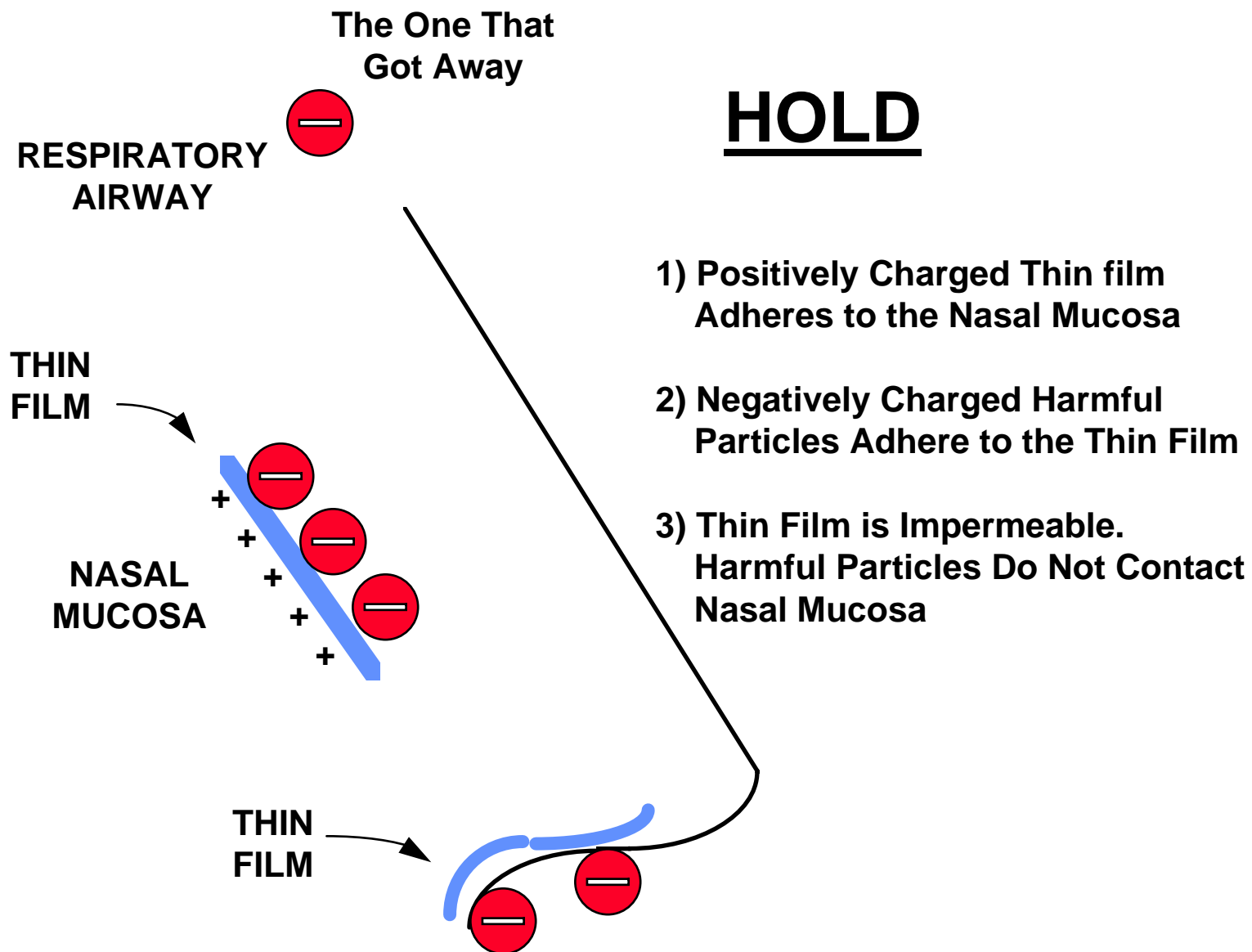
a) CATCH

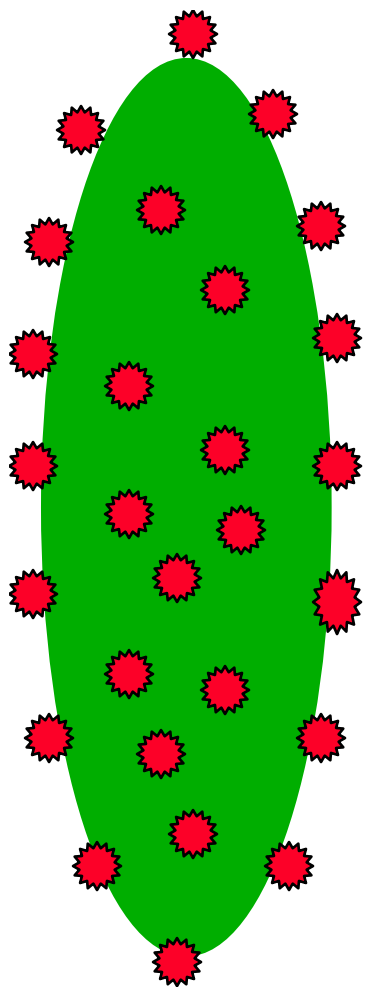
b) HOLD

c) KILL

ELECTROSTATICALLY ATTRACTING







KILL

**CONTACT WITH THE BIOCIDES
INACTIVATES THE
HARMFUL PARTICLES**

Defendant's Allegations of Indefinite Claim Terms

- **Electrostatically Inhibiting**
- **Electrostatically Attracting**
- **Adequate Impermeability**
- **Render[s] Said Particulate Matter Harmless**

INDEFINITENESS

A patent is invalid for indefiniteness if its claims, read in light of the patent's specification and prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014)

INDEFINITENESS

Legal Standard:

“The burden of establishing invalidity based on indefiniteness rests on the party asserting invalidity and must be proven by clear and convincing evidence.”

Defendant's Opening Claim Construction Brief (ECF 38)
Page 3 (ECF Doc. Pg. 7 of 30)

Person Having Ordinary Skill in the Art

A person of ordinary skill is also a person of ordinary creativity, not an automaton.

[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill.

KSR Intern. Co. v. Teleflex, Inc., 550 U.S. 388, 421 (2007)

Person Having Ordinary Skill in the Art

- This person is a pharmaceutical or chemical formulator with a background in biochemistry and physics.
- He or she must have several years background and experience in formulating pharmaceutical compounds.
- He or she may or may not have an undergraduate degree depending on the level of hands-on experience in the field.

35 U.S.C. § 112, First Paragraph

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Defendant's General Allegations

- '802 Patent provides a laundry list of possible ingredients and formulations ...
- No examples, data, or test results demonstrating that any of the formulations “electrostatically attract” harmful particulate matter to the thin film as opposed to other negatively charged particles that are not harmful (such as dust).

**PATENTS ARE NOT REQUIRED TO INCLUDE
TEST DATA OR TEST RESULTS.**

A formulation of the invention comprises:

- at least one quaternary thickener;**
- a preservative;**
- a conditioner;**
- an emulsifier;**
- a biocidic agent; and**
- a neutralizing agent added to adjust a pH in the range of 5.0 to 6.8.**

‘802 Patent at 4:65 – 5:6

A formulation of the invention may further comprise:

- a surfactant;**
- a thickener;**
- an emollient;**
- a humectant; and**
- a binder.**

'802 Patent at 5:9-13

A pharmaceutical formulator would be familiar with the properties of and selection of:

- **Cationic Agents;**
- **Biocidal Agents;**
- **Surfactants;**
- **Thickeners; and**
- **Binders.**

Embodiment From TABLE 10

■ Water	61.925%
■ Phenoxyethanol	1%
■ Lysine HCl	1%
■ Glycerin	9%
■ Glyceryl Acetate	1%
■ Polyquaternium – 10	2.25%
■ Polyquaternium – 67	2%
■ Polyquaternium – 72	1.25%
■ Cocodimonium (etc.)	1.25%
■ Cetrimonium Chloride	2%
■ Polyquaternium – 88	2%
■ Polyquaternium – 22	2%
■ Cetyl Alcohol	4%
■ Cetearyl Alcohol	2.5%
■ Polybutene	5.5%
■ Benzalkonium Chloride	0.25%
■ Hydroxypropyltrimonium	1%
■ Sodium Hydroxide	0.075%

A pharmaceutical formulator would know to substitute ingredients based on factors concerning:

- **Cost** – he or she would know to substitute a less expensive ingredient for an equivalent more expensive one.
- **Regulation** – Requirements of FDA, FTC, EPA, *etc.* (*i.e.*, allowable percentages).
- No undue experimentation required.

However, a patent specification does not concern itself with regulatory or commercialization issues. It is concerned with disclosure and enablement.

A typical pharmaceutical formulator would be able to make and use the disclosed formulations without undue experimentation

35 U.S.C. § 112, Second Paragraph

According to *Nautilus*, to establish an allegation of invalidity of the asserted claims of the '802 Patent due to indefiniteness, the Defendant must show, by clear and convincing evidence, that a person skilled in the art would not comprehend the scope of the claims.

35 U.S.C. § 112, Second Paragraph

According to *Nautilus*, to establish an allegation of invalidity of the asserted claims of the '802 Patent due to indefiniteness, the Defendant must show, by clear and convincing evidence, that a person skilled in the art would not comprehend the scope of the claims.

ELECTROSTATICALLY INHIBITING

Electrostatically Inhibiting

Claim 1 – Original Preamble

- 1. A method for electrostatically preventing harmful particulate matter from infecting an individual through nasal inhalation ...**

Electrostatically Inhibiting

Claim Rejection – 35 U.S.C. § 112, First Paragraph

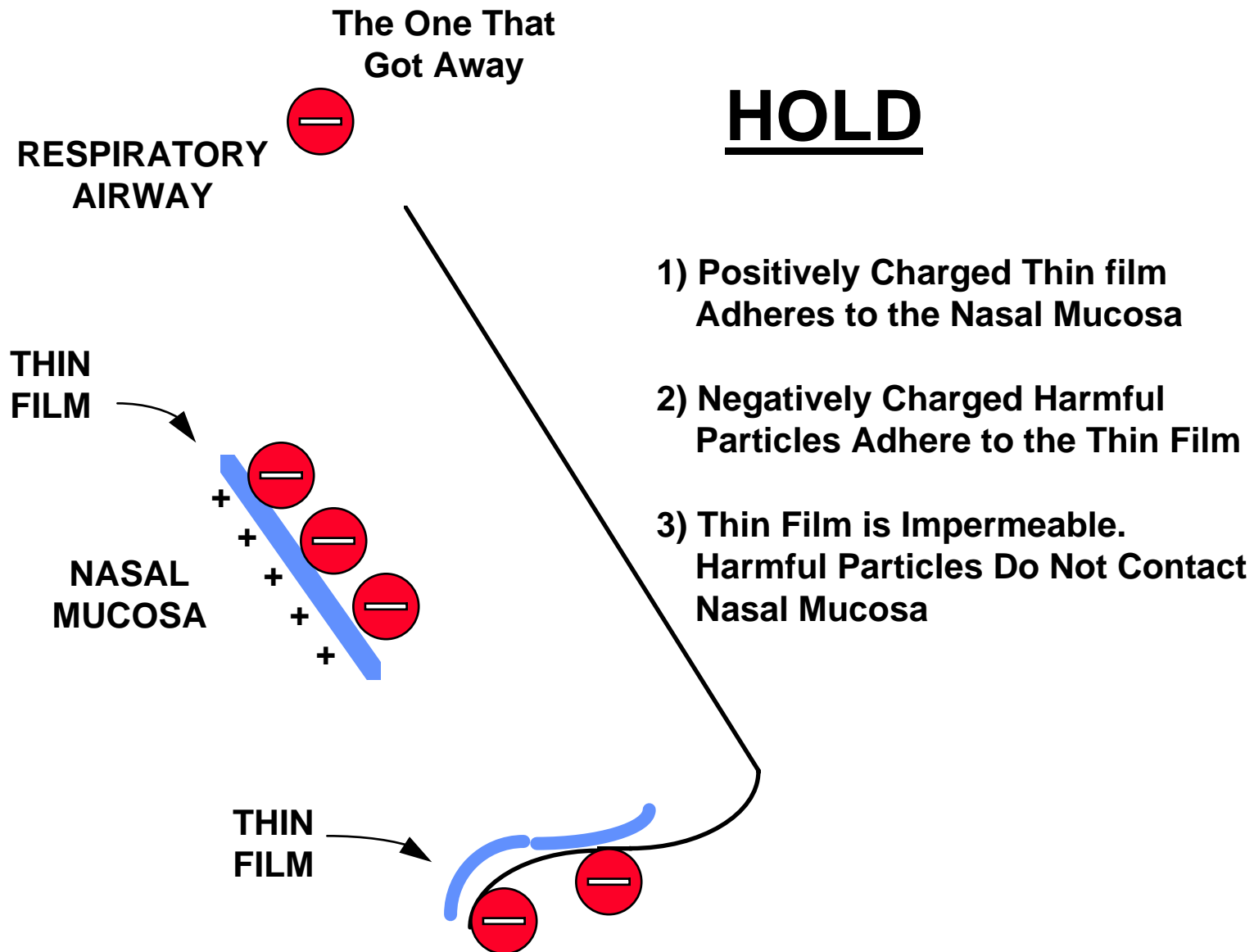
In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be inhibited rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.

Electrostatically Inhibiting

Claim 1 – Amended Preamble

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation ...

PROSECUTION HISTORY ESTOPPEL



Electrostatically Inhibiting

- Clearly, the PTO Examiner defined what is meant by “inhibiting.” The term was understood by the Applicant.
- The Applicant amended the claim, and the application was allowed based on the amendment.
- “Inhibiting” means that while some harmful particles are inactivated, one or more of them can infect the individual.
- “Electrostatically Inhibiting” must be interpreted as inhibiting using electrostatic means. There is no other reasonable interpretation.
- “Electrostatically Inhibiting” is a statement of use for the method of claim 1 and the formulation of claim 2.

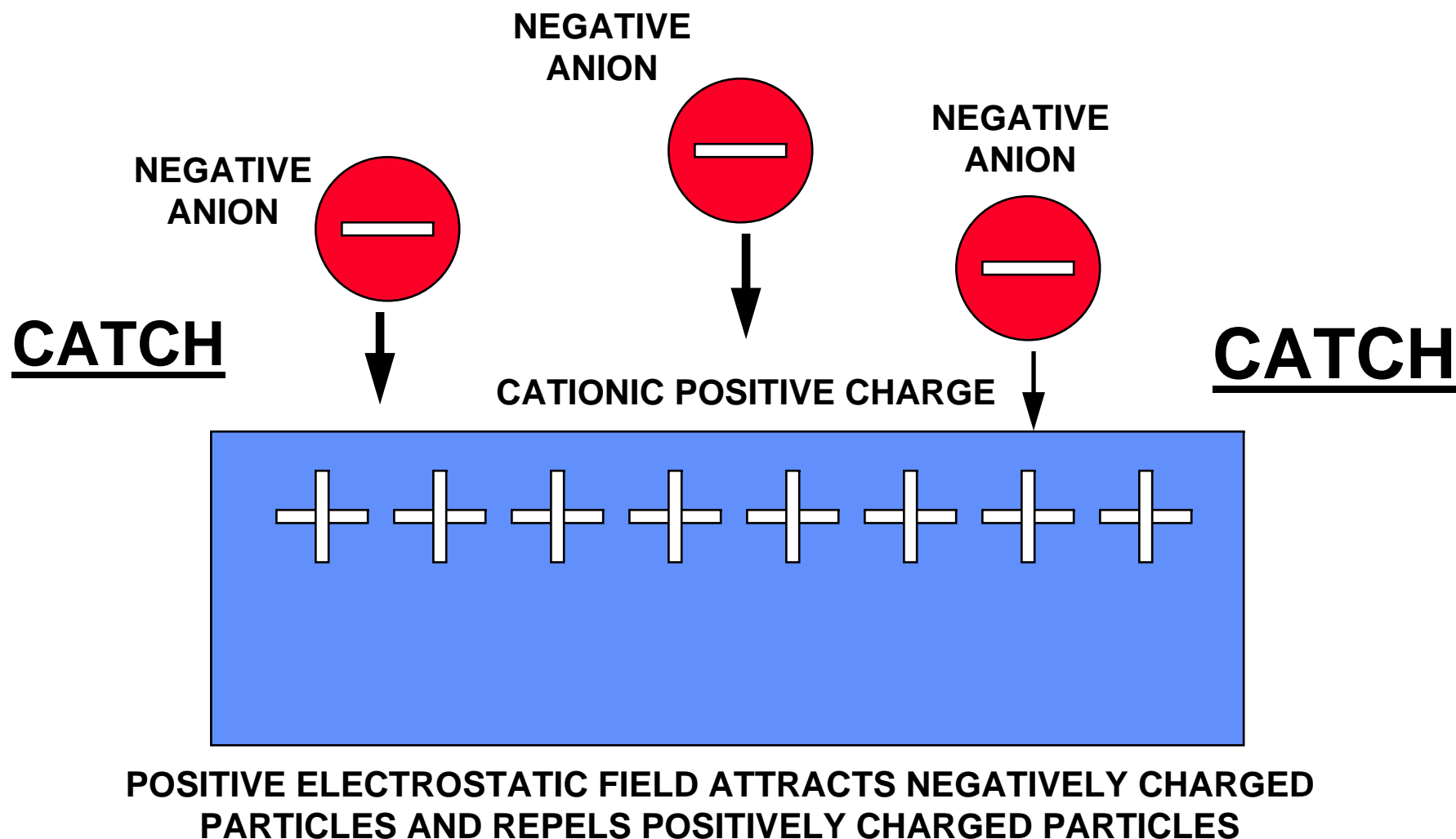
**ELECTROSTATICALLY
ATTRACTING**

Electrostatically Attracting

Claim 2: (CATCH)

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidal agent, and wherein said formulation once applied:
 - a) electrostatically attracts the particulate matter to the thin film;

ELECTROSTATICALLY ATTRACTING



Electrostatically Attracting

- **We begin with the plain meaning of the term.**
- **Presence of a cationic agent in the thin film produces a surface positive electrostatic charge. This is well known.**
- **It is also well known that many harmful particles have a negative electrostatic charge.**
- **By the principles of basic physics, the negatively charged particles will be attracted to the positively charged thin film.**

Electrostatically Attracting

Defendant states:

“[T]he ‘802 Patent is silent as to the specific charge density or other quantitative parameters needed to create the electrostatic field, what magnitude of electrostatic field is necessary to attract oppositely charged contaminants, how far the electrostatic field needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective.”

Electrostatically Attracting

- Test results are not required to prove that an invention follows the basic principles of chemistry and physics. PTO patent examiners and persons skilled in the art are expected to have this knowledge base.
- A patent is not required to be a manufacturing specification.
- Experimentation is permitted as long as such experimentation is not undue.

White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,
713 F.2d 788 (Fed. Cir. 1985).

ADEQUATE IMPERMEABILITY

Adequate Impermeability

“The Present Invention relates to the field of protective compositions against assault by various irritants and noxious substances as well as against assault by assorted microorganisms that typically gain entry into the body through the airway and/or nasal mucosa.”

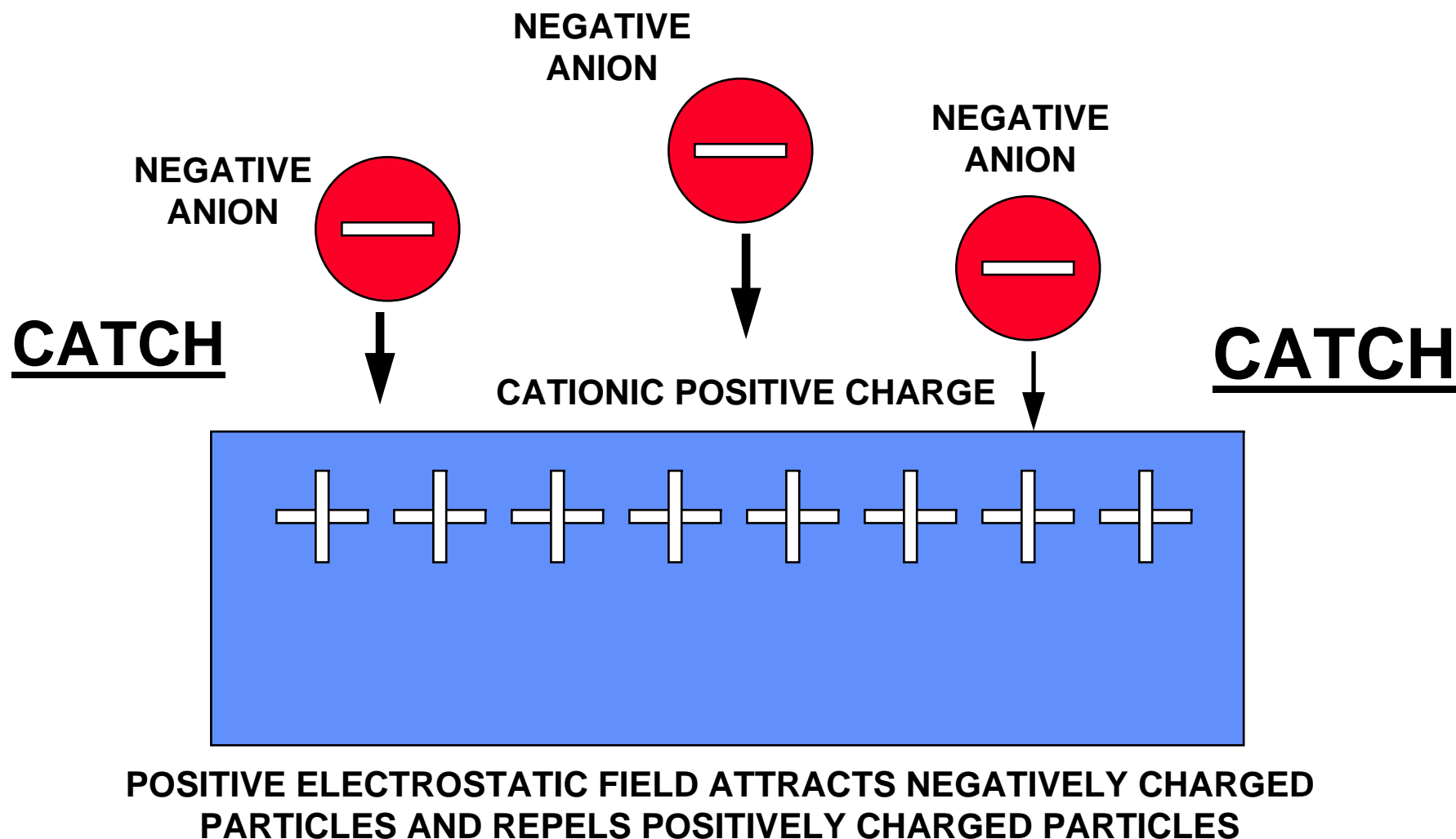
‘802 Patent at 1:58.

Adequate Impermeability

Claim 2 (continued): (HOLD)

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and

ELECTROSTATICALLY ATTRACTING



Adequate Impermeability

- Dictionary Definition of Impermeability:

Impermeability – not permitting passage (as of a fluid) through its substance.

- Dictionary Definition of Adequate:

Adequate – sufficient for specific need or requirement.

Adequate Impermeability

- Adhesion – Bonding of two dissimilar materials.
- Cohesion – Bonding of two similar materials.

Adequate Impermeability

The HOLD function of element (b) in claims 1 & 2:

- Must use adhesion to cause the thin film to stick to the skin or tissue of the individual nasal passages;
- Must use cohesion to make the thin film sticky and tacky, and must use adhesion to cause the harmful particles to stick to the thin film and away from the airway; and
- Must be impermeable enough to prevent the harmful particles to penetrate the thin film thus coming in contact with the nasal mucosa.

Adequate Impermeability

- The word “adequate,” when used in a patent claim is a “term of degree.”
- Terms consisting of the words: *About*, *Essentially*, *Similar*, *Substantially*, and *Type* are commonly used in patent claims.

Adequate Impermeability

A person of ordinary skill can make and use the compositions listed in the specification (§112, ¶1).

- All of the embodiment compositions listed in Tables 1-10 in the specification will perform as in claim 2, provided that the ingredients are kept within the prescribed ranges.
- Whether or not the thin film is viscous enough to prevent penetration of the particles through the thin film can be verified through simple experimentation.
- A person of ordinary skill would be knowledgeable regarding the use of surfactants, emollients, thickeners, and binders to adjust the adhesion and cohesion of the compositions.
- Ingredient concentrations may be varied and adjusted as required to achieve the desired result.

Adequate Impermeability

The word, “impermeability,” as used in Element (b) of claims 1 and 2, means that harmful particles that are captured and held by the thin film do not penetrate the thin film to contact the nasal mucosa.

“Adequate Impermeability,” as used in Element (b) of claims 1 and 2, means that the amount of impermeability achieved by adjusting the adhesion and cohesion of the thin film accomplishes the above function.

RENDERS SAID PARTICULATE MATTER HARMLESS

Renders Said Particulate Matter Harmless

Claim 2 (continued): (KILL)

c) inactivates the particulate matter and renders said particulate matter harmless.

The formulation comprises a biocidic agent that inactivate (kills) microorganisms. [Claim 2 Preamble]

Renders Said Particulate Matter Harmless

A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact with the substrate or skin less harmful.

'802 Patent ABSTRACT

Renders Said Particulate Matter Harmless

It is a further object of the invention to provide that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition.

'802 Patent at 3:3

Renders Said Particulate Matter Harmless

- Inactivation involves (1) holding the particles in place to prevent them from infecting, and (2) killing those particles that are microorganisms.
- Amending the claims to change “preventing” to “inhibiting,” allows for some particles not to be inactivated.
- Those particles that are inactivated can no longer harm the individual.

Renders Said Particulate Matter Harmless

Inactivating harmful particulate matter and rendering them harmless is accomplished by using the three aspects of the method of claim 1 and the formulation of claim 2:

- **CATCH**
- **HOLD**
- **KILL**

Renders Said Particulate Matter Harmless

- While Column 4 of the '802 Patent specification lists disease microorganisms and harmful environmental particulates, the claims do not recite inactivation of all these hazards.
- A patent is permitted to claim less than it discloses in the specification.

Defendant Failed to Prove Claims Indefinite by Clear and Convincing Evidence

- **Electrostatically Inhibiting**
- **Electrostatically Attracting**
- **Adequate Impermeability**
- **Render[s] Said Particulate Matter Harmless**